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Serial No.: 10/766,139
Docket No.: PVI-5541DIVCON
Amendment dated July 26, 2007
Responsive to the Office Action dated June 5, 2007

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REMARKS

Claims 18-19, 21-22, 24-26, 38-39, and 43-58 remain pending.

Claim 54 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In response, Applicant has properly introduced the term "outflow rim."

5 Applicants acknowledge the indication that claims 18-19, 21-22, 24-26, 38-39 and 43 are in condition for allowance.

Presently, only independent claims 44, 50, and 58 stand rejected based on prior art. Each will be addressed in sequence below.

10 Claim 44 stands rejected under 35 U.S.C. §102(e) as being anticipated by Garrison, et al. (USPN 6,425,916), who teach a minimally invasive heart valve having a valve displacer 8 that provides an anchor for a replacement cardiac valve 6 mounted to an expandable support structure 26 (i.e., stent).

Claim 44 stands rejected under 35 U.S.C. §102(e) as being anticipated by Jayaraman (USPN 6,245,102) who discloses a stent valve.

15 Claim 44 stands rejected under 35 U.S.C. §102(b) as being anticipated by Vince (USPN 5,163,953) who discloses a stented prosthetic heart valve.

20 Claim 44 recites a two-part heart valve comprising an expandable base configured to be mechanically coupled to a leaflet subassembly. There is no teaching in Jayaraman or Vince of a two-part heart valve. Accordingly, Applicants disagree with the rejection of claim 44 based on Jayaraman and Vince.

In a previous Office Action, the Examiner cited Figures 14-16 of Thorpe, et al. as showing such a two-part structure, and explained that a "valve is comprised of many parts, each element alone... may each be considered a "part." Now the Examiner identifies "parts" of the valves of both Jayaraman and Vince and means for coupling them together (i.e., stitches 47 in Jayaraman and a "friction fit" in Vince). Applicants note that there is no disclosure of a friction fit between the valve and stent and, in fact, the valve is sutured to the stent ("The valve is sutured to the stent." – (background discussion) col. 1, line33; "In the illustrated embodiment a plurality of

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commissural posts 14 extend upwardly from the body 12 to mount the flaps 11." - col. 2, lines 36-38).

None of these one-part valves teach or suggest a two-part prosthetic heart valve as claimed by Applicants. It is clear from the application description that a two-part heart valve has 5 "two detachable components designed to be assembled post-storage" (see brief description of Figure 6).

To emphasize the two-part valve aspect as opposed to one part valves in general, claim 44 has been amended to specify that the separate tissue-engaging base and leaflet subassembly components are *configured to be stored separately* and the leaflet subassembly is configured to be 10 mechanically coupled to the tissue-engaging base *at the time of an implant procedure* to form a prosthetic heart valve. The one-part valves of the type taught by Jayaraman and Vince are stored as a whole, and assembled in a manufacturing facility.

Moreover, claim 44 has been amended to specify that the leaflet subassembly includes an elastic wireform supporting three heart valve leaflets, wherein the leaflet subassembly is 15 configured to be mechanically coupled to the tissue-engagable base to form the prosthetic valve. Neither Jayaraman nor Vince discloses wireform-supported leaflets which couple to a base. The Examiner identifies in Jayaraman the stent 15 as the base, and the three leaflets 34, 36, 38 as the leaflet subassembly. There is no wireform supporting the leaflets, only the stent 15 supports the leaflets, and it is deemed the base. Likewise, in Vince the Examiner points to the stent coil 12 as 20 the base and the three leaflets 11 as the leaflet subassembly. The stent coil cannot be both the base and the wireform. The stent 10 in Vince "comprises a generally toroidal body 12 formed of a flexible coil of wire. In the illustrated embodiment a plurality of commissural posts 14 extend upwardly from the body 12 to mount the flaps 11. The stent 10 has a unitary structure." Col. 2, lines 34-38.

25 Consequently, Applicants respectfully assert that neither Jayaraman nor Vince anticipates claim 44, which is a two-part valve having a leaflet subassembly, including an elastic wireform supporting three heart valve leaflets, mechanically coupled to a tissue-engagable base.

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Although Garrison et al. disclose a type of two-part valve, Applicant's claim 44 recites a valve wherein a base defines a tubular body having an inflow end and an outflow rim, and three heart valve leaflets of the leaflet subassembly axially spaced from the outflow rim of the tubular body such that the heart valve leaflets are not positioned within the tubular body. In the rejection, 5 the Examiner asserts that the "barbs" or "protrusions" of Garrison et al. are *capable* of mating with any of the openings 14 in the base to result in the claimed relative positioning. However, Applicants note that the leaflets would be within the tubular body of Garrison et al. if the protrusions 34 on the leaflet subassembly mated to one of the openings 14. Garrison et al. provide no other teaching regarding structure for coupling a leaflet subassembly to a tubular body. 10 Fig. 9 of Garrison et al. shows the cardiac valve 6 positioned within the valve displacer 8. The protrusions 34 fit within the three largest openings 14, and would not fit in the other smaller openings. Applicants further note that the upper end of the valve displacer 8 is flared, and much larger than the cardiac valve 6 diameter, rendering a coupling therebetween difficult to imagine. There is simply no suggestion, let alone disclosure, of the construction advanced by the Examiner. 15 The examples noted by the Examiner in Fig. 27 and 28 of Garrison et al. relate to embodiments wherein the leaflet subassembly is not mechanically coupled to the tubular body. To clarify the features of the claimed invention, Applicant has also amended claim 44 to recite "wherein, the three heart valve leaflets are axially spaced from the outflow rim of the tubular body such that the heart valve leaflets are not positioned within the tubular body *after the leaflet subassembly has 20 been mechanically coupled to the tissue-engageable base.*"

Applicants believe that independent claim 44 is now allowable over Jayaraman, Vince, and Garrison et al. Claims 45-49 depend from claim 44 and are also believed to be allowable.

Claim 50 stands rejected under 35 U.S.C. §102(e) as being anticipated by Garrison, et al.

Claim 50 stands rejected under 35 U.S.C. §102(e) as being anticipated by Cribier (USPN 25 6,908,481). Cribier discloses a two-part prosthetic heart valve (e.g., figures 14-15) including a tissue-engaging base that is expandable (first frame 10), and a leaflet subassembly having a support structure (second frame 10') and three valve leaflets (valvular structure 14).

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Claim 50 as amended provides an expandable tissue-engagable base and an expandable leaflet subassembly, both being expandable from a collapsed state to an expanded state. A plurality of axially extending discrete mating connectors on the leaflet subassembly and tissue-engagable base mechanically couple upon axial displacement of the leaflet subassembly in its 5 expanded state toward the expanded tissue-engagable base in its expanded state.

Both Cribier and Garrison, et al. include an inner valve part configured to join upon axial movement and radial expansion to an outer base part. In both Cribier and Garrison, the inner part of the valve moves axially to a positioned within the outer part, *then stops moving axially*, then is radially outwardly expanded to engage the two valve parts. Claim 50, in contrast, specifies that 10 axial displacement of one part toward another part *actuates a mutual coupling mechanism on pairs of axially extending mating connectors* so as to mechanically couple the two parts.

Moreover, claim 50 specifies pairs of *axially extending* mating connectors that mutually couple. This is different than the barbs, hooks, etc. of Cribier and Garrison, et al., because for each axially extending connector on one part of the heart valve there must be a matching one on 15 the other part of the heart valve with which it will mate *upon axial displacement*. In contrast, Cribier states in column 20, lines 33-38 that the second (inner) frame 10' may "have an external surface that is a bit rough to allow better fixation on the first frame when expanded. The bars may also have some hooks to fasten to the first frame." This is not a disclosure or suggestion of providing pairs of mating connectors, let alone ones that couple upon axial displacement toward 20 one another. Garrison, et al. has the protrusions 34 or barbs (not shown) that fit with in openings. These structures radially engage, and are not "axially extending."

Finally, claim 50 has been amended to specify that the discrete mating connectors on the leaflet subassembly and tissue-engagable base mechanically couple upon axial displacement of the leaflet subassembly *in its expanded state* toward the expanded tissue-engagable base *in its expanded state*. Neither Cribier nor Garrison et al. even *permit* axial movement of the valve part 25 with respect to the base part in their expanded states. Once the inner valve part attains its expanded state, it is locked into the outer base part. The same interfering members (barbs,

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protrusions, hooks, etc.) that couple the valve part to the base part restrict axial movement, by definition.

Applicants also wish to point out that dependent claims 52-53 and 55-56 include additional features that are not disclosed or suggested by Cribier. For example, claim 52 specifies 5 that the support structure of the leaflet subassembly comprises an elastic wireform with alternating commissures and cusps, which is not present in Cribier. Claims 55 and 56 further describe the type of coupling between the mating connectors (e.g., snap fit). Applicants fail to understand how the Examiner can find that Cribier has connectors that are joined by axial compression, for example.

10 Applicants therefore respectfully request that the Examiner withdraw the rejection of claim 50 and its dependents on the basis of Cribier and Garrison, et al.

Claim 58 stands rejected under 35 U.S.C. §102(b) as being anticipated by Vince. As mentioned above with respect to claim 44, Vince does not disclose a two-part valve having a leaflet subassembly, including an elastic wireform supporting three heart valve leaflets, 15 mechanically coupled to a tissue-engagable base.

Based on the foregoing amendments and remarks, Applicants believe that claims 18-19, 21-22, 24-26, 38-39, and 43-58 are in condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged contact the undersigned by telephone.

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Respectfully submitted,

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